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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/394,519	09/13/1999	JAMES ZHANG	MBI-0003	4344

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WILEY, REIN & FIELDING, LLP
ATTN: PATENT ADMINISTRATION
1776 K. STREET N.W.
WASHINGTON, DC 20006

EXAMINER

EPPS, JANET L

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 05/16/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/394,519

Applicant(s)

ZHANG ET AL.

Examiner

Janet Epps

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 9-11, 15 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 12-14 and 17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: 12.

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DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1-8, 12-14 and 17 are currently under examination. Claims 9-11, and 15-16 are withdrawn as being drawn to a non-elected invention.

Response to Arguments

3. Claims 1-8, 12-14 and 17 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's arguments filed 12-17-01 and 3-1-02 have been fully considered but they are not persuasive. Applicants traverse the rejection on the grounds that one of skill in the art who would have the full length sequence from the sequence listing, could easily make or produce any of the listed fragments. Furthermore, Applicants argue that the specification clearly sets forth both specific sequences encompassed by the claimed invention beyond the SEQ ID NO sequences themselves, and clearly describes a number of other sequences that one of skill in the art possesses from the use of routine techniques employing the sequence sequences.

Contrary, to Applicant's assertions, Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.) Therefore, although one of skill in the art could, by trial and error experimentation, arrive at other isolated polynucleotides encompassed by the limitations of the instant claims, Applicant's methods of isolation does not support Applicant's assertion that they

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were in possession of the claimed invention at the time of filing of the instant Application. It remains that the claimed polynucleotides encompass all corresponding sequences from other species, mutated sequences, allelic variants, splice variants, sequences that have an unspecified degree of identity (similarity, homology), and so forth. Additionally, it is noted that, the instant claims do not recite any particular function that may be associated with the claimed genus of polynucleotides encompassed by the claimed invention.

Applicants further state that “[t]he PTO then sites to cases, such as Amgen v. Chugai, where the applicant did not even possess the cDNA of the claimed invention encompassing a protein-encoding sequence.” It appears that Applicants have misunderstood the Examiner’s position set forth in the prior Office Action. Amgen v. Chugai, and other cases were cited to clearly set forth the what the courts have decided in regards to satisfying the requirements of 35 USC 112, first paragraph, specifically concerning the requirement for a sufficient written description of the invention. In summary, *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, makes clear that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016, state that an adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. Finally, *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1404, 1405, also cites Fiers v. Revel, and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., and further determines that “[w]hile the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural

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or physical characteristics; in other words, it thus does not describe human insulin cDNA.” The courts have clearly stated that a method of isolating a claimed invention is not sufficient to provide an adequate written description of the claimed invention; a detailed description of the actual chemical structure of the claimed polynucleotide is required.

4. Claim 1 and 5 remain rejected under 35 U.S.C. 102(b) as being anticipated by Rounsley et al. (GenBank Accession No. B29089), or Newman. (GenBank Accession No: T43527, H76020, T14116 or AI100243) for the reasons of record set forth in the Official Action mailed 7-16-01.

Applicant's arguments filed 12-17-01 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that the prior art sequences do not anticipate applicant's amended claim 1, and the claims dependent thereon, as, *inter alia*, they appear to be merely fragments of a gene that has not been expressed in a plant.

First, contrary to Applicant's assertions, the instant claims are not limited to only those nucleotide sequences of a gene that have been expressed in a plant. Secondly, it remains that the instant claims read on (b) a nucleotide sequence encoding a polypeptide comprising a sequence selected from SEQ ID NOs: 20, 38, 44, 46, 106, 124, 126, 128, and 158, *including substitutions, deletions, or insertions*; (f) a nucleotide sequence comprising at least 15 consecutive nucleotides of a polynucleotides sequence encoding an expressed plant polypeptides of SEQ ID NOs: 20, 38, 44, 46, 106, 124, 126, 128, and 158; and (g) the complement of (b). As stated in the prior Official Action, Rounsley et al. discloses a sequence having at least 250 consecutive nucleotides of SEQ ID NO:19 of the instant invention, which encodes the polypeptide according to SEQ ID NO: 20. Therefore, Rounsley et al. discloses an isolated polynucleotide according to claim 1 part

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(f) as described above. Additionally, the nucleotide sequences of Newman meet all the limitations to anticipate claim 1 (f), since each sequence comprises at least 15 consecutive nucleotides of a polynucleotide sequence encoding a polypeptide according to one of SEQ ID NOs: 44, 106, 124, or 128.

5. Claims 1, 5 and 13-14 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Newman (GenBank H76020) in view of Newman et al., for the reasons of record set forth in the Official Action mailed 7-16-01.

Applicant's arguments filed 12-17-01 have been fully considered but they are not persuasive. Applicant traverse the instant rejection on the grounds that the Newman GenBank sequence H76020 does not teach or suggest applicant's amended claim 1. However, as stated above, the nucleotide sequence of Newman (H76020) meets all the limitations of claim 1 (f), e.g., the H76020 sequence contains at least 15 consecutive nucleotides of a polynucleotide encoding a polypeptide according to SEQ ID NO: 44. Applicants also traverse on the grounds that "Applicants have shown in their specification that the recited SEQ Ids of the claims can be used to alter a plant phenotype or trait." Furthermore, Applicants argue, "[t]he rejection offers no reason for expecting that the partial sequence would alter a plant phenotype." However, it is noted that the features upon which applicant relies are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

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Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Epps, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on M-T, Thurs-Friday 8:30AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L Epps, Ph.D.
Examiner
Art Unit 1635

JLE
May 14, 2002


SEAN MCGARRY
PRIMARY EXAMINER
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